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Editor's Choice – Optimal Threshold for the Volume–Outcome Relationship After Open AAA Repair in the Endovascular Era: Analysis of the International Consortium of Vascular Registries

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WHAT THIS PAPER ADDS

In this study by the International Consortium of Vascular Registries, the optimal open abdominal aortic aneurysm (AAA) repair centre volume threshold that is associated with the most significant mortality risk reduction was examined. When assessing open aortic procedures in 11 countries, 13 – 16 procedures/year predicted the most significant reduction in mortality after intact AAA repair. Only 23% of centres met the $\geq$ 13 procedures/year volume threshold. Although open AAA repair preferentially should be performed at centres achieving this target volume threshold, significant re-organisation of aortic care services in several nations is required.

Objective: As open abdominal aortic aneurysm (AAA) repair (OAR) rates decline in the endovascular era, the endorsement of minimum volume thresholds for OAR is increasingly controversial, as this may affect credentialing and training. The purpose of this analysis was to identify an optimal centre volume threshold that is associated with the most significant mortality reduction after OAR, and to determine how this reflects contemporary practice.
Methods: This was an observational study of OARs performed in 11 countries (2010 – 2016) within the International Consortium of Vascular Registry database (n = 178 302). The primary endpoint was post-operative in hospital mortality. Two different methodologies (area under the receiving operating curve optimisation and Markov chain Monte Carlo procedure) were used to determine the optimal centre volume threshold associated with the most significant mortality improvement.
Results: In total, 154 912 (86.9%) intact and 23 390 (13.1%) ruptured AAAs were analysed. The majority (63.1%; n = 112 557) underwent endovascular repair (EVAR) (OAR 36.9%; n = 65 745). A significant inverse relationship between increasing centre volume and lower peri-operative mortality after intact and ruptured OAR was evident ($p < .001$) but not with EVAR. An annual centre volume of between 13 and 16 procedures per year was associated with the most significant mortality reduction after intact OAR (adjusted predicted mortality < 13 procedures/year 4.6%

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[95% confidence interval 4.0% – 5.2%] *vs.* $\geq$ 13 procedures/year 3.1% [95% CI 2.8% – 3.5%]). With the increasing adoption of EVAR, the mean number of OARs per centre (intact + ruptured) decreased significantly (2010 – 2013 = 35.7; 2014 – 2016 = 29.8; $p < .001$). Only 23% of centres ($n = 240/1\,065$) met the $\geq$ 13 procedures/year volume threshold, with significant variation between nations (Germany 11%; Denmark 100%).

Conclusion: An annual centre volume of 13 – 16 OARs per year is the optimal threshold associated with the greatest mortality risk reduction after treatment of intact AAA. However, in the current endovascular era, achieving this threshold requires significant re-organisation of OAR practice delivery in many countries, and would affect provision of non-elective aortic services. Low volume centres continuing to offer OAR should aim to achieve mortality results equivalent to the high volume institution benchmark, using validated data from quality registries to track outcomes.

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INTRODUCTION

Increasing international evidence supports the observation that patients undergoing various complex operations have better outcomes when treated at high volume institutions.[1–3] In fact, the strength of evidence for the volume–outcome association with decreased complication risk after surgery is so compelling that multiple stakeholders such as governmental agencies, insurance providers, patient advocacy groups, physician societies, and clinical practice guidelines endorse minimum volume thresholds for high risk procedures.[4–8] Understandably, there are ongoing impassioned debates regarding the value of establishing specific procedure minimums (e.g., for training or treating acute pathologies such as aortic rupture), owing to the unintended consequences that may occur with forcing the referral of procedures from lower to higher volume centres.[9–12]

Importantly, many low volume centres may achieve excellent mortality outcomes. Therefore, volume thresholds are predominantly necessary if centres do not participate in audited registries that allow them to know that their operative mortality is comparable to outcomes of higher volume centres, which establish an optimal mortality benchmark. In the absence of these data, a proxy for these outcomes is minimum operative volume thresholds.[13] To establish relevant volume thresholds for international guidelines, it is important to analyse high quality data on procedure volume and outcomes that are broadly applicable across multiple nations.

Open abdominal aortic aneurysm (AAA) repair (OAR) is one of 10 high risk operations with outcomes, including complications and mortality, strongly linked to volume.[8] Recent (2019) evaluation of data from 11 countries participating in the International Consortium of Vascular Registries (ICVR) confirmed a significant relationship between operative volume and peri-operative mortality after OAR but refuted such a relationship after EVAR.[1] Although the association between increasing annual centre volume and decreased risk of post-operative mortality after OAR is well established, the optimal volume threshold where this occurs is poorly understood. Conceptually, a continuous relationship between centre volume and outcome could exist; however, stakeholders have identified specific thresholds that associate with optimal outcomes. Different volume benchmarks between 10 and 60 procedures per year have been established by various quality improvement and accreditation organisations.[4,5,14–16] Currently, there is a paucity of international data providing insight into volume thresholds that are applicable to various nations. Moreover, the effect of the increasing adoption of endovascular repair (EVAR), which is supplanting OAR, on volume thresholds is largely unknown.

The current analysis aimed to determine what the optimal volume–outcome threshold is for reducing post-operative mortality after intact OAR, based on the multinational ICVR database. Additionally, how such a volume threshold is reflected in contemporary practice was determined.

METHODS

Registry information

Data from prospectively maintained vascular surgery quality registries in 11 countries were submitted to the Medical Device Epidemiology Network Analytic Centre at Cornell University (MDEpiNet; https://www.mdepinet.net/) for analysis, as describe previously.[1] Eight registries (Australia, Denmark, Hungary, Finland, Malta, New Zealand, Sweden, and the USA) provided de-identified patient level data. Three additional countries (Germany, Norway, the UK) submitted aggregate level data, as differences in European and member state regulations did not allow for individual, patient level analyses from these nations. Details regarding these participating registries such as national registry coverage, validity, and healthcare system features have been published previously.[17–19]

Cohort creation

OAR and EVAR data for primary elective and ruptured AAA from 2010 – 2016 were combined from the eight participating national vascular registries that provided patient level data and the three registries reporting aggregated results (Supplementary Fig. 1). Procedures were excluded if procedure type was not specified, or if patient age, sex, and post-operative mortality were not reported: 155 procedures (0.2%) were excluded. For the overall comparative analysis of crude mortality, all 11 nations contributing data were used. However, owing to limitations of the availability of granular data surrounding specific patient comorbidities

Table 1. Characteristics of patients undergoing abdominal aortic aneurysm (AAA) repair from 2010 to 2016 in the International Consortium of Vascular Registries

	Overall (n = 178 302)	Intact AAA		Ruptured AAA	
		EVAR (n = 105 914)	Open repair (n = 48 998)	EVAR (n = 6 643)	Open repair (n = 16 747)
Age − y	73.2 ± 8.3	74.2 ± 8.1	70.4 ± 8.0	75.3 ± 9.4	74.1 ± 8.8
Sex					
Male	151 024 (84.7)	91 032 (85.9)	40 690 (83.0)	5 473 (82.4)	13 839 (82.6)
Female	27 268 (15.3)	14 882 (14.1)	8 308 (17.0)	1 170 (17.6)	2 908 (17.4)
Diabetes					
No	144 130 (80.8)	84 117 (79.4)	40 943 (83.6)	5 373 (80.9)	13 697 (81.8)
Yes	28 819 (16.2)	18 919 (17.9)	6 776 (13.8)	1 021 (15.4)	2 103 (12.6)
Missing	5 353 (3.0)	2 878 (2.7)	1 279 (2.6)	249 (3.7)	947 (5.7)
Cardiac history					
No	99 152 (55.6)	56 683 (53.5)	28 737 (58.6)	3 733 (56.2)	9 999 (59.7)
Yes	74 198 (41.6)	46 612 (44.0)	19 153 (39.1)	2 633 (39.6)	5 800 (34.6)
Missing	4 952 (2.8)	2 619 (2.5)	1 108 (2.3)	277 (4.2)	948 (5.7)
Creatinine ≥ 150 μmol/L					
No	94 396 (52.9)	58 400 (55.1)	25 697 (52.4)	3 144 (47.3)	7 155 (42.7)
Yes	8 838 (5.0)	4 541 (4.3)	1 639 (3.3)	819 (12.3)	1 839 (11.0)
Missing	75 068 (42.1)	42 973 (40.6)	21 662 (44.2)	2 680 (40.3)	7 753 (46.3)
Year of procedure					
2010–2013	101 157 (56.7)	56 709 (53.5)	30 728 (62.7)	3 267 (49.2)	10 453 (62.4)
2014–2016	77 145 (43.3)	49 205 (46.5)	18 270 (37.3)	3 376 (50.8)	6 294 (37.6)
Procedure					
Open	64 626 (36.2)	–	48 998 (100)	–	16 747 (100)
EVAR	113 676 (63.8)	105 914 (100)	–	6 643 (100)	–
Indication					
Intact	154 912 (86.9)	105 914 (100)	48 998 (100)	–	–
Ruptured	23 390 (13.1)	–	–	6 643 (100)	16 747 (100)
Maximum diameter − cm	6.21 ± 1.49				
In hospital mortality	11 125 (6.2)	1 075 (1.0)	2 295 (4.7)	1 527 (23.0)	6 228 (37.2)

Data are presented as n (%) or mean ± standard deviation. EVAR = endovascular aortic repair.

and/or peri-operative outcomes from three countries (Germany, Norway, and the UK), data from the remaining eight countries were included in the pooled, risk adjusted analysis for the derivation of the threshold.

Exposure and outcome

The exposure variable was centre volume. Hospital annual volumes for elective/non-elective EVAR and OAR were summed separately and averaged across years. The outcome was post-operative mortality. All registries except the Swedish vascular registry (Swedvasc) collected in hospital mortality data after AAA repair. In Sweden, where a cross link to the population registry results in exact survival data, 30 day mortality was used as a proxy.[20]

Covariables

Covariables in the risk adjusted analysis were age, sex, comorbidities, procedure year, and maximum AAA diameter. Comorbidities included were diabetes, cardiac history, and renal dysfunction (http://www.icvr-initiative.org/media/3954/ICVR%20Risk%20Factors.pdf). The analysis was stratified by indication (intact/ruptured) and procedure type (EVAR/OAR).

Statistical analysis

Cohort characteristics were examined by registry, procedure type, and indication. Variation in centre volumes across registries for EVAR and OAR was determined. Proportions of EVAR and OAR performed and mean centre volume for each procedure type for two time periods (2010 − 2013 and 2014 − 2016) were compared using chi square and Student's t tests. Unadjusted mortality analysis was performed separately for four cohorts (intact/ruptured EVAR and intact/ruptured OAR) and compared using chi square tests.

The volume threshold analysis was performed for intact AAA repairs to examine the association between increasing hospital volume (as a continuous variable) and mortality. Multivariable logistic regressions were used with a restricted cubic splines transformation, adjusting for patient characteristics. Based on this model, the focus was on intact OAR to identify a hospital volume threshold below and above which the association between hospital volume and mortality differed. Based on such a threshold, a piecewise logistic regression model[21] was used to quantify the association between hospital volume and mortality.

Two strategies were used to identify an optimal volume threshold: the area under the curve (AUC) approach and the Markov chain Monte Carlo (MCMC) procedure. Area under the receiver operating characteristics (ROC) curve, also

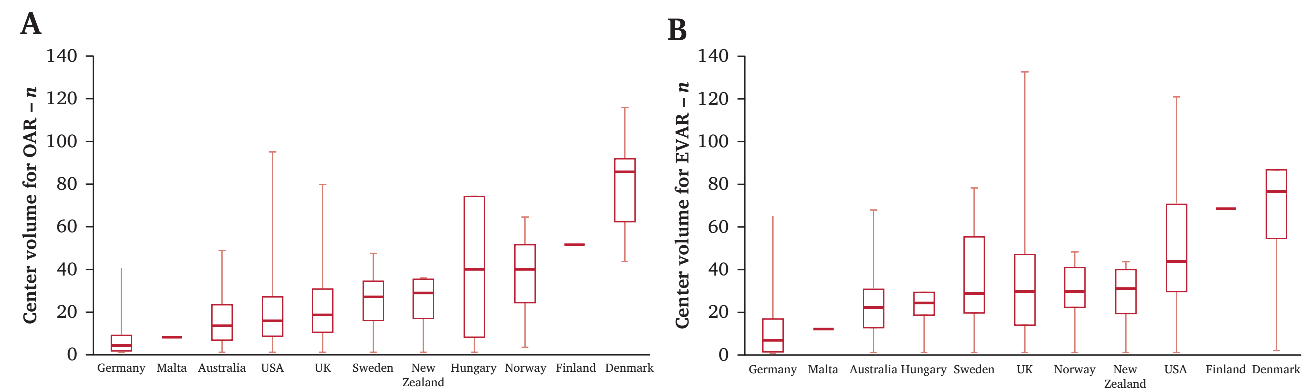

Figure 1. Median annual centre procedure volume and interquartile range by country for (A) open abdominal aortic aneurysm (AAA) repair (OAR) and (B) endovascular AAA repair (EVAR) for 11 different nations. Interquartile range for each nation is determined by the 25th to 75th percentile for centre volume.

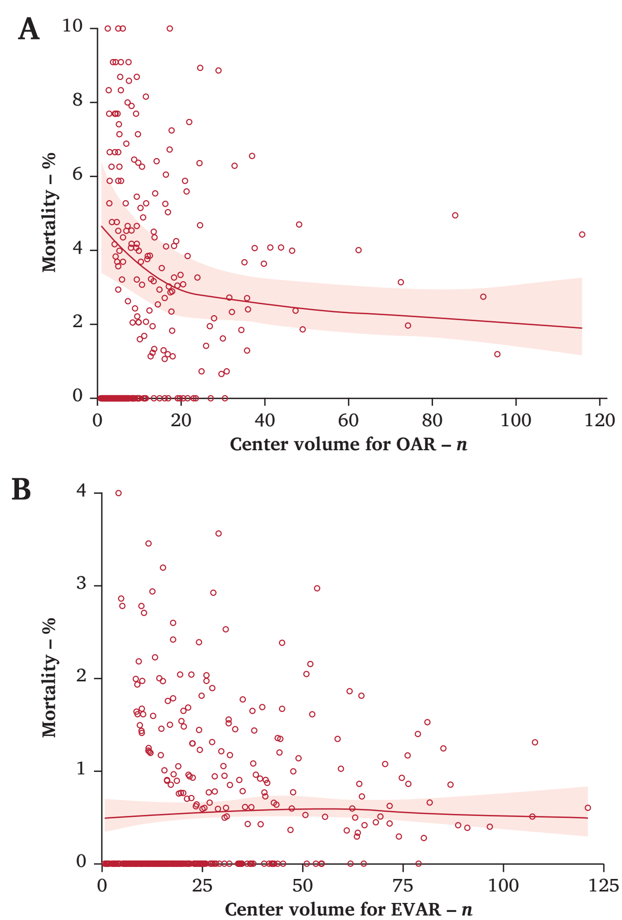

Figure 2. Risk adjusted centre volume and mortality outcome relationship for intact abdominal aortic aneurysm (AAA) repair. (A) The scatter plot highlights a strong volume−outcome relationship is present for open AAA repair (OAR). Specifically, increasing centre volume is associated with lower in hospital mortality. (B) However, no evidence of a centre level volume−outcome relationship within hospital mortality was evident for endovascular aneurysm repair (EVAR).

known as a c-statistic, describes the discrimination of a regression model. A higher AUC indicates a better ability to predict the outcome. For the AUC approach, an attempt was made to find the piecewise logistic regression model with the maximised AUC, and thus the best ability to predict mortality based on covariates.

The second approach used a bootstrap simulation that incorporated a MCMC procedure. MCMC was used to obtain point estimates for a parameter based on a pre-specified prior distribution and the likelihood function. Because the prior distribution should come from current knowledge, it was hypothesised that a piecewise relationship between hospital volume and mortality existed based on the recommended thresholds from vascular societies. Specifically, the Society for Vascular Surgery (SVS) recommends intact OAR to be performed at centres with volumes of ≥ 10 procedures/year.[5] In contrast, the European Society for Vascular Surgery (ESVS) does not endorse aortic repair at centres with a volume of < 20 procedures/year but recommends repair at centres performing ≥ 30 procedures/year.[4] Accordingly, the prior distribution of volume threshold was specified to be uniformly distributed, with a range of $5 - 35$ procedures/year. The MCMC estimate of the volume threshold thus represented the most likely threshold below and above which the association between hospital volume and mortality differed that could be estimated based on prior knowledge and current data. The method was based on prior published investigations and adapted to answer the research question.[22,23]

Finally, volume thresholds were examined when stratifying by the proportion of OAR (above/below 50%) for each centre, among those that contributed data for both EVAR and OAR. A post hoc analysis was performed examining differences in patient characteristics for hospitals with volumes above and below the estimated thresholds. All analyses were performed with SAS 9.3 (SAS Institute, Cary, NC, USA).

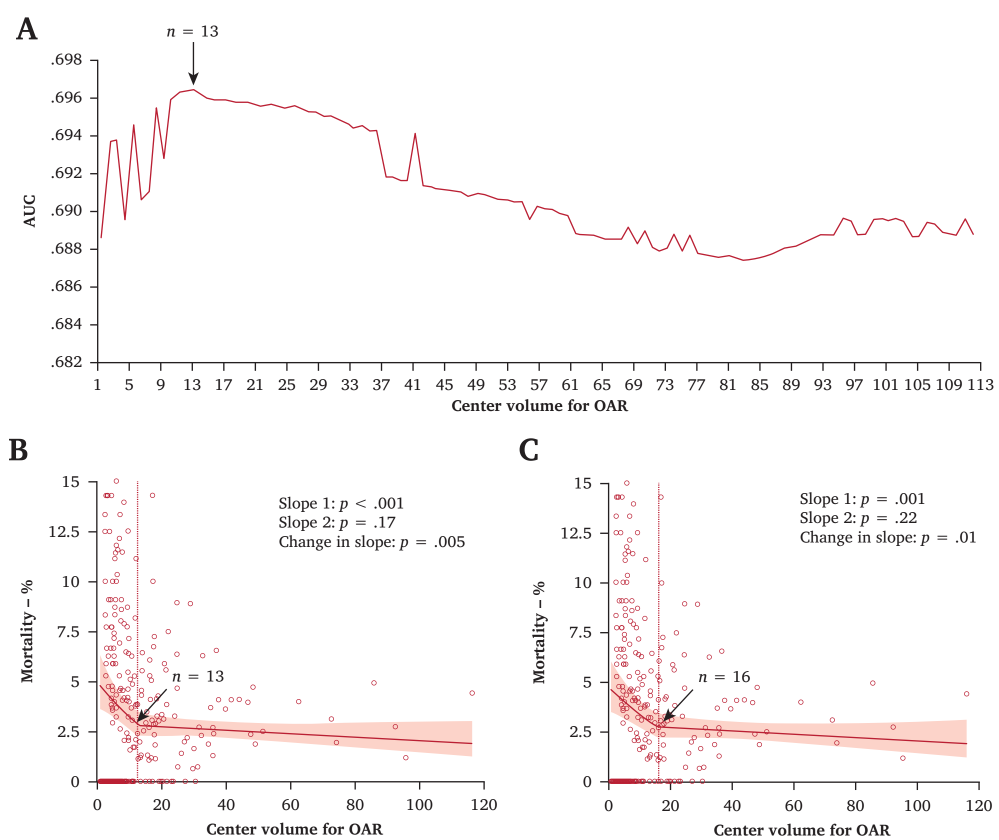

Figure 3. Analysis of optimal annual centre volume threshold for in hospital mortality outcomes after elective open abdominal aortic aneurysm repair (OAR). (A) A piecewise logistic regression model with a volume threshold of 13 procedures per year achieved the maximum area under the receiving operating characteristics curve (AUC) in the c-statistics analysis. (B) Fitting a piecewise logistic regression model with a volume threshold of 13 procedures per year based on the AUC analysis. (C) Fitting a logistic regression model with an annual centre volume of 16 procedures per year based on the Markov chain Monte Carlo (MCMC) analysis, using a pre-specific prior of volume distribution of 5 – 35 procedures per year. Models adjusted for baseline patient characteristics.

RESULTS

Cohort characteristics

A total of 178 302 procedures were analysed (Supplementary Fig. 1). There were 154 912 (86.9%) intact and 23 390 (13.1%) ruptured AAAs. The majority (63.1%; $n = 112\ 557$) underwent EVAR, with the remainder receiving OAR (36.9%; $n = 65\ 745$). EVAR was used in 68.0% of intact *vs.* 28.1% of ruptured AAA repairs. Patient characteristics are presented in Table 1 (cohort characteristics by country are given in Supplementary Table 1).

Variation in centre volume

Median annual OAR and EVAR centre volume varied significantly across countries (Fig. 1). There were significant disparities between median centre volumes for EVAR and OAR; for example, in the USA, the median centre EVAR volume was 2.9 times that of OAR (44 EVAR procedures/year *vs.* 15 OAR procedures/year), while Denmark had a 0.9 fold ratio (76 EVAR procedures/year *vs.* 86 OAR procedures/year).

EVAR adoption, AAA repair volume, and mortality

The proportion of combined intact and ruptured AAA repairs managed by EVAR increased over time from 59.2% (2010 – 2013) to 67.5% (2014 – 2016) ($p < .001$). This observed increase in the adoption of EVAR was associated with changes in mean centre volume for EVAR (intact + ruptured), which increased from 43.1 to 45.2 procedures/year ($p < .001$). Correspondingly, the mean OARs per centre volume (intact + ruptured) decreased from 35.7 to 29.8 procedures ($p < .001$). The overall crude in hospital mortality for all AAA repairs is presented in Table 1.

Threshold analysis

A robust inverse volume–outcome relationship was observed with OAR but not EVAR (Fig. 2A, B). The adjusted predicted mortality decreased from 4.5% to 4.0% to 3.0% as centre volume increased from one to five procedures/year and up to 15 procedures/year (Supplementary Table 2). No significant volume–outcome relationship for in hospital mortality after EVAR was observed in either crude or risk adjusted analysis. Therefore, a piecewise logistic regression

Table 2. Characteristics of patients in the International Consortium of Vascular Registries undergoing open intact abdominal aortic aneurysm (AAA) repair from 2010 to 2016 by two different volume thresholds

	<13 cases/year (n = 4 931)	≥13 cases/year (n = 12 674)	p value	<16 cases/year (n = 5 783)	≥16 cases/year (n = 10 822)	p value
Feature						
Age − y	70.0 ± 8.6	70.2 ± 7.9	.12	70.0 ± 8.6	70.2 ± 7.9	.064
Female	1 083 (22.0)	2 391 (18.9)	.010	1 294 (22.4)	2 180 (20.1)	<.001
Diabetes	734 (14.9)	1 492 (11.8)	<.001	863 (14.9)	1 363 (12.6)	<.001
Cardiac history	2 128 (43.2)	4 517 (35.6)	<.001	2 508 (43.4)	4 137 (38.2)	<.001
Creatinine ≥ 150 μmol/L	325 (7.3)	617 (4.9)	.008	382 (7.2)	560 (6.1)	.009
Maximum AAA diameter − cm	6.10 ± 1.56	6.14 ± 1.44	.18	6.11 ± 1.54	6.14 ± 1.44	.22
In hospital mortality − %						
Unadjusted	4.4	3.2		4.2	3.2	
Adjusted predicted*	4.6	3.1		4.4	3.1	

Data are presented as n (%) or mean ± standard deviation unless stated otherwise.
* Based on restricted cubic spline model.

model was hypothesised, and subsequent threshold analyses only focused on the intact OAR cohort.

In the first threshold analysis using the AUC (Fig. 3A, B), the optimal inflection point that maximised the AUC for a piecewise regression model of the association between centre volume and in hospital mortality was 13 procedures/year (adjusted predicted mortality < 13 procedures/year 4.6% [95% confidence interval (CI) 4.0% − 5.2% *vs.* ≥ 13 procedures 3.1% [95% CI 2.8% − 3.5%]). When applying the piecewise regression there was a significant decrease in patient mortality when centre volume increased from one to 12 procedures/year (p < .001). When centre volume reached 13 procedures/year, further volume increase was associated with a small but non-significant decrease in mortality (p = .17).

In the MCMC analysis with a prior of 5 − 35 procedures/year, the threshold identified was ≥ 16 procedures/year (with 95% of the bootstrap estimates between five and 30 procedures/year) (Fig. 3C). This meant that 16 procedures/year was the mostly likely threshold above and below which the relationship between mortality and centre volume differed based on prior knowledge and observations.

Contemporary practice and centre volume threshold

Next, centres were defined as being "high" or "low" volume based upon the thresholds identified with the two statistical methodologies. A lower proportion of patients operated at high volume hospitals (e.g., ≥ 13 and/or ≥ 16 procedures/year) were female, or had a pre-operative history of diabetes, cardiac, and/or renal disease (Table 2). Compared with high volume hospitals, patients undergoing OAR at low volume centres had higher unadjusted and adjusted predicted in hospital mortality (Table 2).

Among all centres examined, only 23% (n = 242/1 067) performed ≥ 13 OARs/year, which is the lowest identified threshold.[5] The proportion of centres achieving a ≥ 13 or ≥ 16 procedures/year threshold by nation are presented in Table 3. In Denmark, Norway, Sweden, and the UK, > 50% of centres currently achieved both benchmarks. In contrast, in Germany, 8% of centres achieved ≥ 16 OARs/year, while 11% performed ≥ 13 OARs/year. When exploring the associated threshold based upon the proportion of repair types, centres with < 50% of OARs had continuous improvement in mortality as volume increased, with mortality being < 3% at a volume threshold of nine procedures/year. In contrast, centres performing ≥ 50% of AAAs using open repair had an AUC threshold of 10 procedures per year (MCMC threshold: 19 for < 50% OAR and 17 for ≥ 50% OAR).

DISCUSSION

This analysis provides a comprehensive assessment of optimal hospital annual volume thresholds that are associated with reduced in hospital mortality after intact OAR using a large multinational dataset. Significant differences in patient selection and in hospital mortality were identified between centres that did or did not achieve these thresholds. Concordantly, high volume institutions had statistically significantly better outcomes compared with centres below these thresholds, in both crude and risk adjusted analysis.

Table 3. Proportion of centres in the International Consortium of Vascular Registries achieving the optimal annual centre volume threshold for open intact abdominal aortic aneurysm repair from 2010 to 2016

	AUS	DNK	FIN	HUN	MLT	NZL	NOR	SWE	GBR	USA
Centres − n	108	7	1	25	1	15	17	30	117	187
Volume ≥13	14 (13.0)	7 (100)	1 (100)	4 (16)	0	8 (53)	12 (71)	18 (60)	79 (67.5)	36 (19.3)
Volume ≥16	12 (11.1)	7 (100)	1 (100)	4 (16)	0	6 (40)	12 (71)	16 (53)	65 (55.6)	16 (8.6)

Data are presented as n (%). AUS = Australia; DNK = Denmark; FIN = Finland; HUN = Hungary; MLT = Malta; NZL = New Zealand; NOR = Norway; SWE = Sweden; GBR = United Kingdom; USA = United States.

These observations were identified during a contemporaneous era of increasing EVAR adoption, which continues to supplant OAR. Despite the reciprocal decrease in OAR and guidelines,[4,5,19] advocating referral to high volume institutions, a majority of repairs in many countries continue to occur at low volume centres.

The association between hospital volume and AAA repair mortality has been examined in individual country analyses and numerous large, retrospective cohort studies.[10,24–26] McPhee *et al.* identified that annualised centre volume of both EVAR and OAR was predictive of post-operative ruptured AAA mortality in the National Inpatient Sample.[26] Similarly, a large nationwide administrative data analysis from Germany demonstrated that hospital volume was inversely associated with mortality after OAR and EVAR.[3] Additionally, administrative data analyses, using different statistical methods, from the UK have previously confirmed that variations in AAA repair outcomes were partially attributed to volume.[24,27] Prior work confirmed the improved in hospital mortality associated with higher volume hospitals performing OAR of intact and ruptured AAA.[1] Although no relationship were found between volume and early post-operative mortality for EVAR, it is important to highlight that this does not preclude the presence of a volume—outcome relationship in EVAR when assessing other long term outcomes. For example, EVAR has a higher risk of late failure than OAR, and adequate anatomical procedure selection and device implantation are key factors affecting long term EVAR failure and need for re-intervention. The potential relationship between hospital volume and long term outcomes after EVAR requires further focused studies.

The current in depth analysis sought to identify an optimal annual centre volume threshold that was associated with a reduced in hospital mortality risk for intact OAR. The relevance and importance of this are highlighted by the fact that the evidence describing the hospital volume—outcome relationship is well established for specific procedures across multiple medical and surgical disciplines, including vascular surgery.[10,28,29] As a result, quality improvement and accreditation organisations such as Leapfrog, the Agency for Healthcare Research and Quality, The Joint Commission, and the American Heart Association each include their own volume benchmarks (ranging from 20 to 50 procedures per year; $<$ 5% 30 day mortality and/or $>$ 97% survival)[8] for centres performing OAR.[29] The current international vascular society guidelines quote a minimum volume of $\geq$ 10 (SVS)[5] or $\geq$ 30 (ESVS)[4] operations/year.

Despite endorsed volume standards, elective OAR continues to occur predominantly at centres not meeting minimum thresholds, as indicated by this analysis. Naturally, organisation and regionalisation of AAA repair services are affected by geographical constraints, which may require the ability of aortic surgery, especially ruptured AAA repair, to be delivered in a remote area, despite low volumes. However, the practice of low volume aortic surgery is not confined to geographically isolated regions, but occurs in high population density geographical areas such as New York State.[30] There are several important barriers to the regionalisation of OAR to high volume centres, including access to hospitals with experienced surgeons working in mature care systems, as well as other complex psychosocial, economic and/or geographical variables.[8,31]

Given these challenges, low volume centres continuing to offer OAR need to examine and refine processes of care that will further improve outcomes to meet the benchmarks of higher volume centres. Low volume centres may analyse and compare outcomes by participating in prospectively collected quality registries that have established auditing and validation processes. Independently of centre volume, facilities that track their OAR outcomes through registry engagement will be able to compare results consistently and ensure they are achieving the best outcomes.

Centralising open aortic services to meet the suggested volume threshold levels would require significant changes in the organisation of aortic care in many countries. This pattern of regionalisation has already occurred in some countries such as the UK, where the National Health Service utilises a “hub and spoke” model for AAA care delivery facilitated through a robust vascular surgical centre network that directs OAR to a single high volume hospital.[16] As a result of this centralisation of services, the number of centres performing AAA repair in England decreased from 99 in 2010 to 68 in 2018.[32] However, such an organisational shift needs to account for the delivery of acute vascular surgical care to ensure the health of the population it services. Most importantly, a change in the provision of elective OAR needs to be matched to adequate resources to ensure timely availability of ruptured AAA repair, for example with EVAR or to swift and established patient transfer algorithms for those requiring open repair. Accordingly, the organisation of aortic services needs to be tailored to the specific geographical and general healthcare system challenges for each country.

Although centralisation of aortic services seems prudent based upon the current evidence linking improved outcomes with higher centre volume, there are important unintended consequences to consider. Specifically, implications related to complex psychosocial, economic, geographical, and training related variables need to be addressed, as stakeholders consider endorsement and subsequent enforcement of any specific volume threshold. Importantly, time from diagnosis to treatment may be adversely affected by regionalisation, which is especially important when considering patients with non-elective presentations. Finally, many low volume centres achieve exemplary outcomes with OAR so it remains unclear whether these centres should no longer be allowed to provide these services.

The increasing rates of EVAR use in the management of AAA have been reported previously but significant variation in adoption has occurred internationally.[17] The implication of greater proportions of intact and ruptured AAA being treated by EVAR is a concordant decrease in OAR volumes. The unintended consequence is fewer centres with experienced surgeons who are able to perform OAR and train the next generation of surgeons. Ideally, OAR training should only occur at institutions with sufficient annual procedure volumes to support these efforts. This may result in certain programmes being designated as aortic surgery training centres and/or increased dependence on simulation.[33] Although not a central focus of the current analysis, important differences in patient selection were identified between high and low volume centres. These differences may become further magnified as fewer centres and surgeons routinely perform OAR.

The results of the current analysis should be interpreted within the context of its limitations. Firstly, although this represents the largest multinational analysis to identify optimal OAR thresholds, the retrospective nature of the study design means that not all bias related to selection differences that undoubtedly existed between high and low volume centres could be accounted for in the modelling. Because this was not a randomised trial, definitive numbers needed to treat for high *vs.* low volume centres could not be reported, and the contribution that centralisation has on the AAA care services of some nations was not accounted for in the risk adjustment. Importantly, not all registries provide 100% procedure capture for each nation. Notably, data from the USA Vascular Quality Initiative registry include a non-random sampling of ∼18% of all centres in the USA, and data from Finland are based on procedures performed in the Helsinki metropolitan area. Therefore, it is possible that additional selection bias is introduced into the aggregated analysis. Additionally, the analysis examined within hospital mortality and may underestimate the 30 day mortality that is frequently reported.

The current analysis includes data from different healthcare systems (e.g., fee for service *vs.* single payer systems), which could have influenced variation in referral, patient selection, and outcomes. There is no information on other known predictors of peri-operative mortality, hospital attributes, surgeon experience, or surgeon specific volumes, which is important to consider in risk adjustment and might affect the results. It is recognised that the volume threshold may evolve as processes of care and variation in practice occurs, so iterative re-assessments of these benchmarks are probably needed over time. Finally, although no volume—outcome relationship for short term mortality after EVAR was identified; longer term follow up on re-intervention and aortic related mortality is needed to better understand these associations. Lastly, it was elected to examine elective OAR, but a parallel analysis for ruptured presentations was not presented. Thresholds that may be relevant for non-elective OAR cannot be commented on.

In conclusion, this report provides the first description of a minimum volume threshold analysis for OAR based on international data from across Europe, Australasia, the USA, and Canada. The identified thresholds of 13 — 16 operations/year may serve as a foundation for the ongoing debate surrounding endorsement of annual centre volume thresholds in many nations. With the increasing use of EVAR, a minority of centres currently achieve these volume thresholds for OAR, indicating a potential need for future reorganisation of aortic services in several countries. Low volume centres that continue to offer OAR should aim to achieve mortality outcomes equivalent to high volume centre benchmarks, using validated data from quality registries.

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CONFLICTS OF INTEREST

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2021.02.018.

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